

**REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32, 34-41, 101, and 104-107 are pending in this application. Claims 1, 2, 3, 40, 41, and 101 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

Support for the amendment to claims 1, 2, 40, and 41 can be found throughout the specification as originally filed. For example, support for the amendment to recite “transfer means communicating between the input storage container and the chamber for transferring the cells from the storage container continuing to the chamber” can be found, for instance, on page 9, line 4 – page 10, line 5, and on page 129, paragraph 6. Support for the amendment to recite “a further transfer means for transferring a volume of the agent into the chamber, including a reservoir of the agent” can be found, for instance, on page 9, line 4 – page 10, line 5, on page 10, lines 25-28, and on page 130, paragraph 9. Further, support for the amendment to recite that the further transfer means is disposable can be found, for example, on page 13, lines 5-13. No new matter is added.

Support for the amendment to claim 101 can be found throughout the specification as originally filed, for instance, on page 9, line 4 – page 10, line 5, and on page 10, line 30 – page 11, line 10. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

**II. THE REJECTION UNDER 35 U.S.C. § 112 IS OVERCOME**

Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32, and 34-41 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. According to the Office

Action, the recitation that the chamber, input storage container, and output container are “disposable” in claims 1, 2, 40, and 41 is allegedly indefinite, because the term is subject to interpretation between routineers. This rejection is traversed.

Initially, Applicant reminds that claims must be given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In the present case, Applicant asserts that one of ordinary skill in the art would understand that the term “disposable” as used in the claims based on the disclosures in the specification as originally filed. For instance, the specification indicates that the disposable components of the device may be “disposed of after each procedure.” (Specification, page 23, lines 25-26). The specification also indicates that, after the process of using the device is complete, the disposable components of the device, such as the chamber, “may be disposed of.” (Specification, page 29, lines 29-32). Thus, based on the specification, the skilled artisan would understand the meaning of the term “disposable,” including its metes and bounds, as recited in the instant claims.

Accordingly, Applicant asserts that the instant claims are not indefinite, and respectfully requests reconsideration and withdrawal of the rejection under § 112, second paragraph.

### **III. THE REJECTIONS UNDER 35 U.S.C. § 102 ARE OVERCOME**

Claims 1-3, 15, 19, 20, 22, 23, 25, 26, 28-32, and 34-41 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Koketsu et al. (U.S. Patent No. 5,834,423), by Barenholz et al. (U.S. Patent No. 4,812,314), or by Reddy et al. (U.S. Patent No. 6,054,587). These rejections are traversed and will be addressed collectively.

Initially, Applicant respectfully notes that “[a] rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference.” *In re Buszard* 504 F.3d 1364, 1366 (Fed. Cir. 2007) (citing *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994); *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001) (“Invalidity on the ground of ‘anticipation’ requires lack of novelty of the invention as claimed . . . that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim.”)).

With this in mind, Applicant asserts that the cited references do not anticipate the instant claims. Instant independent claims 1, 2, 40, and 41 recite that the claimed device comprises “transfer means communicating between the input storage container and the chamber for

transferring the cells from the storage container continuing to the chamber” and “a further transfer means for transferring a volume of the agent into the chamber, including a reservoir of the agent.” One of ordinary skill in the art would recognize that none of the cited references teach a further transfer means for transferring a volume of the agent to the chamber, a further transfer means that includes a reservoir of the agent, or a further transfer means that is disposable. The only alleged transfer means recognized by the Office Action in these cited references is the unscrewing of the roller bottle cap in the roller bottle in Koketsu et al. (*see* Office Action, page 5), the unscrewing of the cap to a culture flask in Barenholz et al. (*see* Office Action, page 6), and the unscrewing of the cap of the Falcon tube in Reddy et al. (*see* Office Action, page 6). The skilled artisan would understand that these alleged transfer means of the cited references cannot meet the disclosures in the claims, as they cannot comprise a volume of the agent and cannot be disposable.

For at least these reasons, Applicant asserts that none of Koketsu et al., Barenholz et al., or Reddy et al. anticipates claims 1, 2, 40, or 41, or claims 3, 15, 19, 20, 22, 23, 25, 26, 28-32, and 34-39 that depend therefrom. Accordingly, Applicant requests reconsideration and withdrawal of the rejections under Section 102.

#### **IV. THE REJECTION UNDER 35 U.S.C. § 103 IS OVERCOME**

Claims 101, 104, 105, and 107 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Palsson et al. (U.S. Patent No. 5,888,807). This rejection is traversed.

Initially, Applicant respectfully notes that in determining obviousness one must consider, *inter alia*, the differences between the prior art devices and the claimed invention. *See Graham v. John Deere Co.*, 86 S. Ct. 684 (1966); *see also KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1733-34 (2007). Also, for an invention to be obvious, a person of ordinary skill in the art needs a reason to attempt to carry out the claimed process and needs a reasonable expectation of success in doing so. *Pharmastem Therapeutics, Inc. v. Viacell, Inc.* 491 F.3d 1342, 1360 (2007) (citations omitted).

Applicant notes that claim 101 is amended to herein recite that the device comprises “a carbon dioxide control means for introducing an amount of carbon dioxide into the heated incubation chamber.” Palsson et al. does not teach or even suggest a device comprising a means for introducing an amount of carbon dioxide into a heated incubation chamber; rather, Palsson et al. states that carbon dioxide “must be removed,” and discusses the use of a gas permeable

membrane. (*See* Palsson et al., col. 7, line 12 – col. 8, line 4). Such disclosures would not lead the skilled artisan to a device that comprises a means to introduce carbon dioxide.

For at least these reasons, Applicant asserts that Palsson et al. does not render claim 101, or claims 104, 105, and 107 that depend therefrom, unpatentable. Accordingly, Applicant requests reconsideration and withdrawal of the rejection under Section 103.